IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA ex rel. TIFFANY MONTCRIEFF, ROBERTA MARTINEZ, and ALICIA BURNETT, Plaintiffs, vs. **PERIPHERAL VASCULAR ASSOCIATES P.A.,** Defendant.	Civil Action No. SA-17-CV-00317-XR

RELATORS' MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANT PERIPHERAL VASCULAR ASSOCIATES, P.A.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page No(s).

Cases

Statutes

TO THE HONORABLE UNITED STATES DISTRICT JUDGE XAVIER RODRIGUEZ:

Pursuant to Federal Rule of Civil Procedure 56, Relators Tiffany Montcrieff, Alicia Burnett, and Roberta Martinez move for summary judgment against Defendant Peripheral Vascular Associates, P.A. ("PVA") on the entirety of Relators' claims under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), for presenting false claims; 31 U.S.C. § 3729(a)(1)(B), for making or using false records or statements material to payment or approval of false claims; or alternatively, 31 U.S.C. § 3729(a)(1)(G), retention of proceeds to which not entitled. Relators request oral argument.

Alternatively, Relators seek partial summary judgment for violation of the False Claims Act causes of action above referenced for the following categories of claims:

(1) 8,757 claims related to "testing only" patients, submitted by Defendant to Medicare and other federal payers using false CPT codes that misrepresented that a physician's interpretation and reporting had been rendered;

(2) 29,954 claims related to patients on which PVA conducted both an "Evaluation and Management" patient visit and a vascular study on the same day, where PVA illegally billed Medicare and other federal payers for both, without having completed a separate, stand-alone report reflecting performance of the professional component (i.e., double billing); and

(3) 1,690 claims to Medicare and other federal payers on which PVA misrepresented the identity of the physician who performed interpretation of the vascular studies.

Relators further alternatively seek partial summary judgment as to all elements of PVA's violations of the False Claims Act *other than* whether PVA violated the False Claims Act "knowingly"; i.e., reserving only determination of the element of scienter for the trier of fact.

I. INTRODUCTION

Defendant PVA violated fundamental billing rules, charging Medicare for tens of thousands of "vascular laboratory" services that it had not provided.

All Medicare claims for payment are submitted on a paper or electronic version of a "CMS-1500" form. The provider is required to list the services being billed for on the form using Current Procedural Terminology (CPT) codes. CPT codes, and their definitions, are published by the American Medical Association (AMA). Knowingly using the wrong CPT code on a bill to Medicare gives rise to False Claims Act (FCA) liability.

The CPT codes that PVA used to bill Medicare for its vascular studies explicitly require a physician's interpretation, and documentation of that interpretation in the form of a report. The interpretation and report are an integral part of the service, and the service is not complete without it. As one of PVA's former physicians, Dr. Lyssa Ochoa, testified: "You cannot bill for the physician's services until you have finalized that report." Ex. 8 (Ochoa Dep. Tr.), at 33:8-9.[1]

Misbilling of CPT codes is one of the most common forms of FCA violations in the healthcare field. *See, e.g., United States ex rel. Emerson Park v. Legacy Heart Care, LLC*, No. 3:16-CV-0803-S, 2019 WL 4450371, at *9 (N.D. Tex. Sept. 17, 2019) ("Relator alleged that Remaining Defendants are liable under the FCA for 'upcoding [E&M] services to the highest level billing codes'—i.e., charging Medicare for unnecessary services or services that were never actually provided. A defendant charging the Government for services not actually provided is a staple FCA violation."); *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 755 (S.D. Tex. 2010) ("The amounts Medicare pays physicians for services provided in conjunction with a procedure performed at a hospital are based on Current Procedural Terminology ('CPT') codes published by the American Medical Association. Physicians typically provide the CPT code and submit claims for payment on Form CMS–1500.").

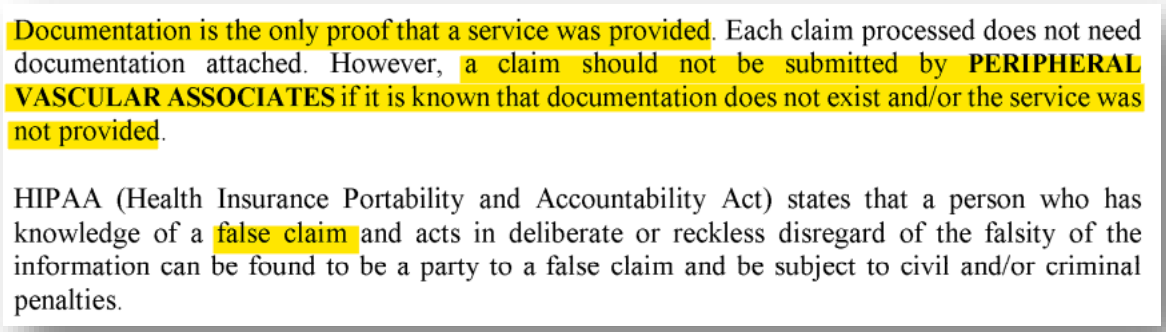
PVA's internal policies confirm its understanding of these concepts. For example, its "Medical Documentation & Coding Compliance Pledge," states:

- PVA "subscribes to the documentation standards published by the Health Care Financing Administration **and the American Medical Association**";

[1] Unless otherwise noted, all referenced exhibits are attached to the Declaration of Sarvenaz Fahimi, filed herewith.

- "All services provided should be documented and coded"; and
- "It should be understood that the patient's chart is the only defense against of [sic] a claim of fraud or abuse. **If it is not documented, it never happened and cannot be billed**."

Ex. 20, at DEF000694 (emphasis added); Appendix in Support of Motion (App.) No. 20. The same concepts are repeated in PVA's Policy Manual, in even stronger language:



Documentation is the only proof that a service was provided. Each claim processed does not need documentation attached. However, a claim should not be submitted by **PERIPHERAL VASCULAR ASSOCIATES** if it is known that documentation does not exist and/or the service was not provided.

HIPAA (Health Insurance Portability and Accountability Act) states that a person who has knowledge of a false claim and acts in deliberate or reckless disregard of the falsity of the information can be found to be a party to a false claim and be subject to civil and/or criminal penalties.

Ex. 20 at DEF000718 (emphasis added); App. No. 60.

In 2017, recognizing that its billing practices were out of bounds, PVA finally decided to change its ways, and began waiting to bill until studies were actually completed. *See* App. Nos. 16, 46, 47. The minutes from an April 5, 2017 meeting of PVA's Vascular Lab Committee, describe the project as a "structure shift," designed to **"Allow[] for Compliance,"** by **"billing after study interpreted."** Ex. 30 at DEF007691 (emphasis added); App. No. 79. Unfortunately, after a few short months, faced with decreased cash flow, PVA abandoned the project, and returned to violating the law.

Evidence such as this, detailed herein, leaves no genuine issue in dispute for trial, and Relators respectfully submit that summary judgment is warranted.

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II. FACTUAL BACKGROUND

A. Background Statement of Uncontested Facts

From at least January 1, 2014 to the present:

1. PVA billed Medicare and other federal payers for vascular studies and E/M Services using the electronic version of the CMS-1500 form. App. No. 1.
2. The CMS-1500 includes several explicit certifications by the provider, including that the claim submitted: (1) is "true, accurate and complete"; (2) "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment…"; and (3) that the "services on this form were medically necessary and personally furnished by me…" App. No. 2.
3. PVA billed Medicare and other federal payers for vascular studies and E/M Services using CPT codes. App. No. 3.
4. For all vascular studies performed in its vascular laboratories, PVA billed using the "global" CPT code, without modifier. App. No. 7; *see also* App. Nos. 4-6.
5. Other than for a brief period in early 2017, described below, PVA billed vascular studies using "global" CPT codes, without modifier, regardless of whether a final report had been generated and signed by an interpreting physician. App. No. 9.
6. For 24.2% of vascular studies billed by PVA to Medicare, PVA used "global" CPT codes, without modifier, despite no final report having been generated and signed in the MedStreaming system by an interpreting physician. App. No. 10.
7. The PVA physicians' interpretations of vascular studies may be reflected in one or both of two places: (1) a final, electronically signed MedStreaming report; and (2) an "encounter note" in the AllScripts Electronic Medical Record system reflecting a patient visit with a PVA physician, electronically signed by the PVA physician. App. No. 11.
8. Some of the individuals on which PVA performed vascular studies were referred to PVA only for the studies, and not for evaluation, management, or treatment. PVA referred to these as "testing only" patients. App. No. 12.
9. "Testing only" patients did not receive E/M Services from PVA. App. No. 13.
10. With respect to "testing only" patients, there are no encounter notes in AllScripts reflecting a physician visit or physician interpretation of vascular studies. App. No. 14.
11. In 2017, PVA attempted to modify its practices to ensure that bills for vascular studies were not submitted until a final report in MedStreaming was generated and signed by a PVA physician. App. No. 16.

12. After several months, PVA returned to its prior practice of billing for the global service upon completion of the technical component, regardless of whether a final MedStreaming report had been generated and signed. App. No. 17.

13. For certain tests, during some of the pertinent time period, PVA utilized a "pool" reading system, pursuant to which any number of PVA physicians could review and sign MedStreaming reports, irrespective of the physician name that appeared on the charge to a payer. App. No. 18.

B. PVA billed Medicare using an electronic version of the CMS-1500, and using CPT codes published by the American Medical Association.

PVA, like all Medicare providers, was required to, and did, submit its claims for reimbursement on a paper or electronic version of the CMS-1500 form. *See* App. No. 1; Ex. 4 [Britt Dep. Tr.] at 181:5-9; *see also U.S. ex rel. Bennett v. Medtronic, Inc*., 747 F. Supp. 2d 745, 755 (S.D. Tex. 2010); *United States v. Krizek*, 859 F. Supp. 5, 7–8 (D.D.C. 1994).

The CMS-1500 includes several explicit certifications by the provider, including that the claim submitted: (1) is "true, accurate and complete"; (2) "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment…"; and (3) that the "services on this form were medically necessary and personally furnished by me…" Ex. 40, p. 2; App. No. 2; *see also Krizek*, 859 F. Supp. at 7–8 ("The submission of a claim on the HCFA 1500 form is a certification by the provider to the government of the correctness of the information submitted and, among other things, that the services were performed by the provider....'").

The provider is required to list the services being billed for on the CMS-1500 form using Current Procedural Terminology (CPT) codes, which include a 5-digit code, and in appropriate circumstances, a 2-character "modifier." App. Nos. 4-6. CPT codes, and their definitions, are

published by the American Medical Association (AMA). *See U.S. ex rel. Stewart v. Louisiana Clinic*, No. CIV.A. 99-1767, 2003 WL 21283944, at *3 (E.D. La. June 4, 2003).

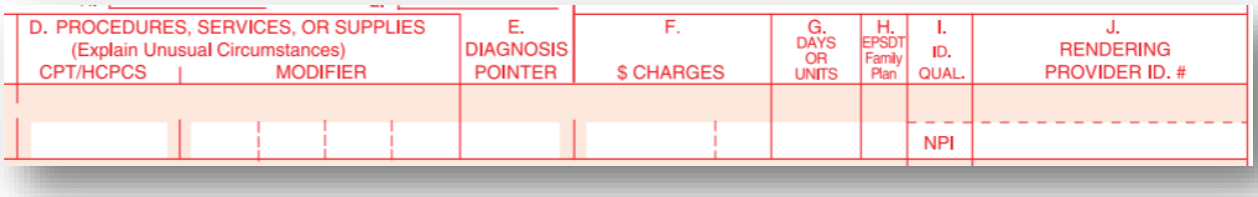


Fig. 1: Excerpt from CMS-1500 form, Ex. 40.

Use of the AMA's CPT codes for radiologic and other diagnostic procedures billed to Medicare has been mandated by Federal Regulation since at least 2002. *See* 45 C.F.R. § 162.1002; *see also* App. No. 4; Ex. 37 (Medicare Claims Processing Manual: Chapter 13 – Radiology Services and Other Diagnostic Procedures), § 10.1 ("Acceptable HCPCS codes for radiology and other diagnostic services are taken primarily from the CPT-4 portion of HCPCS. . . . Charges must be reported by HCPCS code."); *see also* Ex. 2 (Burrow Dep. Tr.), at 25:15-25:23 ("A. So a CPT code is the -- is a number or sometimes a number and a letter that represents the ultrasound procedure. So, like, a carotid is a 93880. Q. And those are codes that are recognized by payors such as Medicare. Is that correct? A. Correct.").

C. PVA used CPT codes that misrepresented its services on thousands of claims to Medicare.

On thousands of occasions, PVA knowingly billed Medicare using CPT codes that misrepresented its services. In the case of ultrasound services and other venous studies of the type at issue in this case, the 5-digit CPT codes encompass both a "professional" and "technical" component. *See* App. No. 5. The technical component is the performance of the service by the non-physician staff (typically, a licensed sonographer). *See* App. Nos. 5-6. The professional component is the interpretation of the results by a physician, and documentation of that interpretation in a report. *See* App. No. 5. These components can in some circumstances be billed separately, using a two-character CPT "modifier." App. Nos. 5-6. Billing the CPT code

without a modifier, however, signifies that all components of the service have been performed. Doing so is sometimes referred to as billing on a "global" basis. App. Nos. 6-7.

PVA knowingly violated these rules by submitting thousands of global CPT codes for vascular studies without having performed the "professional" half of the service. This miscoding was the result of two standard practices at PVA: (1) PVA always billed on a global basis (*see* Ex. 2 (Burrow Dep. Tr.) at 38:23-39:7); and (2) PVA triggered the billing process upon performance of the vascular study by the technologist, irrespective of whether a PVA physician had yet reviewed or interpreted the study (*see* Ex. 19 at DEF0181011). App. Nos. 7, 8, 9, 10;.

As discussed in the following section, the physician's interpretation must be documented in a written report. App. No. 8. PVA uses a software program, MedStreaming, to create and sign its written reports, and MedStreaming records data reflecting if and when a physician has signed. App. No. 11. Accordingly, whether PVA had completed an interpretation before it billed can be determined based on a review of PVA's MedStreaming and billing data.

D. The text of the AMA manual covering the CPT codes used by PVA requires completion of a written report reflecting the physician's interpretation.

The services at issue in this case fall within the umbrella of Radiology, and are primarily categorized as "Non-Invasive Vascular Diagnostic Studies," which the AMA's CPT manual describes as follows:

> Vascular studies include patient care required to perform the studies, supervision of the studies and interpretation of study results with copies for patient records of hard copy output with analysis of all data, including bidirectional vascular flow or imaging when provided.

Ex. 45, at 694; App. No. 21. PVA's Compliance Officer, Dr. Alsabrook, agreed that this paragraph describes "the basic requirements for billing any noninvasive vascular diagnostic study." Ex. 1 (Alsabrook Dep. Tr.), at 33:21-34:10; App. No. 21.

The CPT Manual also contains an introductory section pertinent to Radiology, entitled "Radiology Guidelines (Including Nuclear Medicine and Diagnostic Ultrasound)." Those Radiology Guidelines end with a paragraph entitled "Written Report(s)," which states:

> A written report, signed by the interpreting physician, should be considered an integral part of a radiologic procedure or interpretation.

Ex. 45 at 475; App. No. 23.

The CPT Manual also contains an introduction to "Diagnostic Ultrasound" services, which reiterates the requirement of a written report:

> Use of ultrasound, without thorough evaluation of organ(s) or anatomic region, image documentation, and final, written report, is not separately reportable.

Ex. 45 at 495; App. No. 24;

Accordingly, the global CPT code (which includes the Professional Component) cannot be billed unless the physician's interpretation of study results has been completed, as reflected in a written report in the patient record. App. No. 25. PVA's Compliance Officer, Dr. Grady Alsabrook, admitted this in his deposition. *See* Ex. 1 (Alsabrook Dep. Tr.), 36:25-37:9 ("Q. And when PVA is submitting a bill to Medicare for the global service of a vascular diagnostic study, would you agree with me that the steps that you describe for the professional component need to be documented somewhere? A. I would agree that the steps of the -- of the professional component, as I've previously stated, need to be documented, yes."); App. No. 25.

This rule is also reiterated in the Medicare Claims Processing Manual, Chapter 13 – Radiology Services and Other Diagnostic Procedures, in section 20.1, entitled "Professional Component (PC): "The interpretation of a diagnostic procedure includes a written report." Ex. 37 at ALEXANDER000425; App. No. 4.

PVA ran afoul of this rule with respect to 24.2% of the vascular studies it performed and billed, tainting 29.5% of the reimbursement payments it received (including 29.89% of all payments from Medicare Part B). *See* Ex. 200 (Nye Supp. Report), at Exs. 2 & 4d; App. No. 26.

E. PVA's excuses do not justify its violations.

PVA admits that it frequently did not complete a signed, interpretive written report in its reporting system (MedStreaming) prior to billing for the services. App. No. 27. In fact, its billers are instructed to submit bills once a study is "*ready* to be read by a physician." Exh. 19 (DEF0181011) (emphasis added); App. No. 28. Its only defense appears to be that in those

cases, its physicians' written interpretations are reflected outside of its MedStreaming system, in the notes of patient visits that occurred on the same day as the vascular studies. App. No. 29.

As detailed in the following sections, there are two fundamental flaws with PVA's defense: (1) for many patients, there was no visit with a PVA physician—they were only referred to PVA for a study and interpretation, and returned to their own non-PVA physician for treatment; and (2) for patients who had both a visit with a PVA physician and a vascular study, the CPT manual is crystal clear that an interpretive note in a patient chart does not allow billing of *both* the patient visit (an "Evaluation and Management" code in CPT parlance) and the interpretation of a study; instead, a stand-alone report must be generated. *See* App. Nos. 30-31.

1. PVA submitted 11,728 charges for which there was no report in MedStreaming, and no Evaluation and Management patient visit.

Most of the individuals on which PVA conducts vascular studies are its own patients; i.e., PVA's physicians are managing the patient's care. App. No. 32. PVA also, however, conducts vascular studies that are ordered by non-PVA physicians, on patients who are under the care of those non-PVA physicians. App. No. 32. PVA refers to those individuals as "testing only" patients. PVA's physicians do not see those patients, but only interpret the vascular studies conducted by PVA's technicians, the results of which are transmitted back to the referring physician for diagnosis, management, and treatment. *See* Ex. 10 (Hembling Dep. Tr.), at 32:20-33:11; App. No. 32.

For these "testing only" patients, there is nowhere besides a MedStreaming report that the PVA physicians' interpretations could appear. *See* App. Nos. 11-14; 30. There is no patient visit note, because there is no patient visit. *Id.* PVA's Compliance Officer, Dr. Alsabrook, and its Technical Director, Barbara Burrow, both confirmed in deposition that for "testing only" patients, there would be no report other than in MedStreaming. Ex. 1 (Alsabrook Dep. Tr.), at 94:2-94:16; Ex. 2 (Burrow Dep. Tr.), at 119:24-120:23.

Patient JL provides an example of this category of false claims. *See* Exs. 24-26. JL was referred to PVA for testing by a non-PVA physician, Dr. Juan E. Rubio, in April 2015. *See* Ex.

26, at PVA0005257. PVA performed a Cerebrovascular Duplex Scan on JL on April 21, 2015. *Id.* at PVA0005255. The MedStreaming report from that study was not signed by a PVA physician until almost *two years later*, on March 9, 2017. *See* Ex. 24. Medicare, however, was billed for the service shortly after the scan, and PVA received $88.23 from Medicare on May 7, 2015. *See* Ex. 25. There is no reflection in PVA's medical record for JL of any patient visit, or any other interpretation of the scan, other than the 2017 MedStreaming report. *See* Ex. 26. Accordingly, for patients such as JL who did not have an E/M visit, there is nowhere besides the MedStreaming Report that a physician's interpretation could be reflected. App. No. 39.

Using PVA's medical record and billing data, Dr. Nye has calculated that PVA submitted 11,728 charges for vascular studies performed on "testing only" patients such as JL, for which there was no signed MedStreaming report at the time the charge was submitted. *See* Ex. 200 (Nye Supp. Report) at Ex. 2; App. No. 33.

Dr. Nye's analysis is corroborated by manual review of 121 "testing only" patients produced by PVA in discovery, all of which follow the same pattern as JL: they received a vascular study only, never saw a PVA physician, and interpretations of their results is reflected nowhere but in the MedStreaming report. *See* Exs. 74-195; *see* also App. Nos. 13-14, 30, 32, 40; Ex. 53 (index of "testing only" patients). With no physician E/M visit, there is nowhere besides the MedStreaming report that a physician's interpretation could be reflected. Accordingly, these 11,728 claims[2] were false, as they represented that they had completed a vascular study when in fact no physician interpretation had occurred or been documented. App. No. 33.

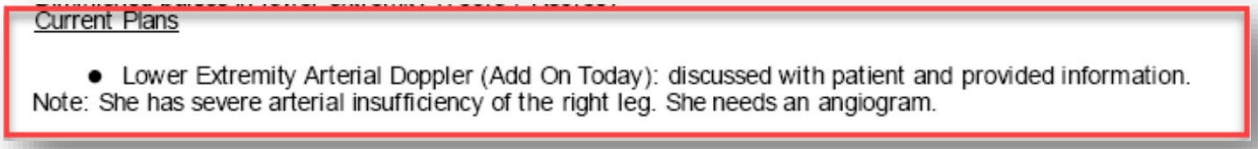
2. PVA double-billed where a patient visit and vascular study interpretation are reflected only in the patient visit note.

The remainder of PVA's false charges—57,450 in total—were for patients that PVA was treating. In other words, PVA's physicians had a visit with the patient, and a vascular study was performed on the same day. Patient visits are referred to as "E/M Services," in billing parlance

[2] These claims are filtered down to Medicare-payors in Section II.E below.

(short for "Evaluation and Management"). App. Nos. 41-43. Like vascular studies, E/M Services are billed using the CPT codes published by the AMA. App. Nos. 31, 41.

PVA's defense to its submission of vascular study charges without a completed MedStreaming report is that the substance of the physician's interpretation is reported not in MedStreaming, but in the note describing the E/M patient visit. App. No. 42. For example,


Current Plans

- Lower Extremity Arterial Doppler (Add On Today): discussed with patient and provided information.

Note: She has severe arterial insufficiency of the right leg. She needs an angiogram.

PVA's expert, Melissa Scott, asserts that the following sentences, appearing at the end of a patient visit note, constitute a valid written report for purposes of billing a vascular study:

Fig. 3: E/M note from Melissa Scott Report (Ex. 202), page 37.

Unfortunately for PVA, the CPT definitions explicitly prohibit billing for both an E/M Service and a vascular study based on a brief note such as this in a patient chart, as follows:

> The actual performance and/or interpretation of diagnostic tests/studies ordered during a patient encounter are not included in the levels of E/M services. Physician performance of diagnostic tests/studies for which specific CPT® codes are available may be reported separately, in addition to the appropriate E/M code. The physician's interpretation of the results of diagnostic tests/studies (ie, professional component) *with preparation of a separate distinctly identifiable signed written report* may also be reported separately, using the appropriate CPT® code with modifier 26 appended.

Ex. 45, at p. 6 (emphasis added). In other words, a note such as this allows PVA to bill for an E/M Service, using the E/M CPT codes, but not a vascular study in addition. PVA can only bill for both if it has prepared a "separate distinctly identifiable signed written report," documenting its physicians' interpretation. App. No. 43.

As discussed in Section II.F.3.d below, a variety of healthcare industry publications reemphasize this prohibition, evidencing PVA's recklessness and deliberate ignorance. App. No. 44. PVA's defense thus runs it square into even worse problems—not only did it bill for services not rendered, but "double-dipped," billing for two services with documentation only for one.

PVA billed Medicare and TriCare payors for both an E/M CPT code and a global vascular study CPT code, without a separate, stand-alone report, on 55,566 occasions, and was reimbursed $5,625,548 for those false vascular studies, as detailed in Section III.E below.

F. PVA acted in reckless disregard, deliberate ignorance, or with actual knowledge that its claims were false.

1. In 2017, PVA recognized that is practices were noncompliant, but continued them anyway.

As described above, it was PVA's standard practice to trigger its billing process as soon as the vascular study was conducted on the patient by the technologist, and to bill on a "global" basis, irrespective of whether a PVA physician had completed a written report, or even looked at the results. *See* Ex. 2 (Burrow Dep. Tr.) at 110:10-23; App. No. 45. Because PVA's physicians did not timely review the studies and complete written reports, this inevitably led to billing Medicare and other payors for services that had not been rendered. PVA knew this was occurring, and in 2017, finally decided to do something about it. App. Nos. 16, 46, 47, 79. The 2017 compliance project, and documents surrounding it, show that PVA knew that is practices were not compliant.

The reasons for the 2017 compliance project, and its implementation, were summarized in multiple documents. The minutes from a February 8, 2017 meeting of PVA's Vascular Lab Committee lay out PVA's three motives for the "[t]ransition to billing after studies are read," as (1) "Ensure billed to appropriate physician," (2) "Ensure no audit requests for incomplete medical records," and (3) "Allow for docs to read each others stuff." Ex. 31 at DEF007698; App. No. 47. PVA thus knew its practices subjected it to the very problems now being addressed in this False Claims Act lawsuit: "incomplete medical records," payor audits, misbilling under the wrong provider, and inadequate patient care due to missing reports.

Over the coming months, PVA attempted to institute the compliance plan, with a two-pronged approach: (1) not billing until the interpretation and report was completed; and (2) decreasing the delays in physician interpretation. The minutes from an April 5, 2017 meeting of

PVA's Vascular Lab Committee, describe the project as a "structure shift," designed to **"Allow[] for Compliance," by "billing after study interpreted."** Ex. 32 at DEF007691 (emphasis added). A document shared between Brian Hembling and Barbara Burrow entitled "Vascular Lab Billing Process change," confirmed that: "The billing/coding process was changed this year. It is now required for a study to have a completed report to be signed and read before it is billed." Ex. 31 at DEF007085.

PVA's "Goal" was a "5 business day average billing time for vascular lab by the end of the year." Ex. 31 at DEF007085; *see also* App. No. 48. "Physicians were having issues reading reports in a timely fashion." *Id.* at DEF007086. Accordingly, "Read groups were created so that any physician could read." *Id.; see also* Ex. 30 (the first available PVA physician would read a vascular study that had "not been read for over 48 hrs."); App. Nos. 18, 48.

Unfortunately, PVA's effort was weak, and short lived. At the outset of the project, PVA feared that by waiting to bill until services were complete, there could be a "35% change in vascular lab office related revenue." Ex. 32 at DEF007698. As of April, PVA could not find a way to get its physicians to timely read studies so that billing would not be delayed. *See id.* at DEF007703 ("Takes significantly longer to bill exam"); DEF007704 ("Still having issues with physicians signing studies."). By the June meeting of the Vascular Lab Committee, PVA had given up, and reverted to its prior practice of billing once the study was *ready* to be read (i.e., in "QA" status). *See* Ex. 32 at DEF007700 ("Coding Process Changed; Changed again; Now study only set to QA, then charged / billed."); Ex. 2 (Burrow Dep. Tr.), at 108:21-109:11 (Q. [W]hat were the substantive changes that were made? A. Well, for a little bit we were billing and coding after the report was signed and read.").

Also of note, internal e-mails indicate that many years prior, before PVA began using MedStreaming in 2014, PVA may have actually been compliant, and awaited final reports before billing. For example, in a 2013 e-mail string between Barbara Burrow and several other PVA employees regarding a set of patients from PVA's Hondo location, Ms. Burrow wrote: "I looked at the studies that were scanned in. Most of them were not actually interpreted and cannot be

billed until they are. I have spoken with Al, who will speak to the doctors." Ex. 14 (emphasis added); *see also* Ex. 12 (2012 e-mail from Ms. Burrow to a PVA physician urging him to sign his reports, and that "One is being held for billing awaiting the complete report.").

These eras of compliance, no matter how remote or brief, demonstrate that PVA was well aware of the billing rules, and knowingly violated them.

2. PVA closely tracked delays in physician interpretation and reporting of vascular studies, and knew that studies were not being read.

Internal documents show that PVA closely tracked delays in physician interpretation and reporting of vascular studies, and knew that studies were not being read. App. No. 50. For example, Barbara Burrow ran a detailed report from data in MedStreaming that tracked the average time it took for PVA to generate a preliminary report in MedStreaming, and for PVA's physicians to then read and sign those reports, at each of PVA's "downtown" locations ("DT Zone"), on a monthly basis. Ex. 22. It shows monthly averages of, at its very best, 4 days to complete a studies. *Id.* Most months far exceeded that, including an average of 29 days in January 2016. *Id.*

Burrow began running these and other reports in mid-2016. App. No. 51. Their purpose, as she described it in an e-mail to PVA physicians Dr. Fiala and Dr. Macris, was to "[r]eport how long it takes the tech to complete the report after the appointment, and how long it takes after it is completed for the physician to sign. [] **ICAVL states the whole process should take no more than 4 business days**." Ex. 29 at DEF022557 (emphasis added); *see also* Ex. 2 (Burrow Dep. Tr.), at 83:2-83:13 ("We had a personal goal for PVA to get studies read quickly. For a regular study, the goal is 48 hours.").

Well before Barbara Burrow began running these reports, PVA knew that it had a serious problem with physicians failing to read studies and prepare reports. For example, in a 2012 e-mail, a PVA employee, Monica Garcia, told Barbara Burrow that she "came across some unsigned reports by Dr. Sykes," and asked Ms. Burrow: "Does he have a lot of unsigned reports?" Ms. Burrow responded, "318," to which Ms. Garcia replied, "Yikes." Ex. 11.

Similarly, in 2013, one of PVA's hospital accounts complained that "it appears we do not routinely receive dictations in a timely manner from your office on a regular basis. Sometime these studies are up to two weeks old before they reach our door." Ex. 15.

PVA has thus known for years that its vascular studies were not being timely read. Nonetheless, PVA continued its practice of triggering the global billing process as soon as the patient left the office.

3. PVA ran afoul of its own compliance policies, the policies of its accreditation society, and general industry standards.

a. PVA's compliance policies.

PVA did not follow its own written compliance policies, several of which relate to the conduct at issue, nor did PVA make any real effort to do so.

For example, PVA's compliance policies include a "Medical Documentation & Coding Compliance Pledge," pursuant to which PVA employees were to affirm: "*I understand that I am expected to adhere to the standards of documentation, medical coding, and conduct described in this pledge so that the Practice may fulfill its obligations to observe federal, state, and local laws affecting patients, colleagues, and institutional partners.*" Ex. 20 at DEF000693 (italics in original); *see also* App. No. 53. The second page of the Compliance Pledge includes a summary of the False Claims Act, followed by a paragraph on "Documentation," which begins:

> **Documentation.** The Practice subscribes to the documentation standards published by the Health Care Financing Administration **and the American Medical Association** as published and in effect January 1, 1998 and as periodically updated via CMS bulletins. **Procedural codes** as well as diagnosis codes **should only be selected which are supported in the chart. All services provided should be documented and coded.** Documentation in the chart should support a diagnosis code to its highest level of specificity. It should be understood that the patient's chart is the only defense against of [sic] a claim of fraud or abuse. **If it is not documented, it never happened and cannot be billed**.

Id. at DEF000694 (emphasis added); *see also* App. No. 54.

The Compliance Pledge further describes a supposed internal "[e]valuation of billing practices," "[t]o insure compliance with Federal, State, and local laws." *Id.* at DEF000695. The

Pledge states: "It is anticipated that the compliance officer will review or cause to be reviewed approximately ten claims per provider per year for services provided during the preceding three-month period." *Id.* "**Under and over coding issues will be identified** in the evaluations along with recommended corrective actions." *Id.* Unfortunately, as testified by PVA's Compliance Officer, Dr. Alsabrook, no such reviews ever took place. Ex. 1 (Alsabrook Tr.), at 21:17-21.

Attached to PVA's Compliance Pledge is its "Compliance Plan." Ex. 20 at DEF000696. The Compliance Plan includes an introductory section entitled "High Risk Areas," which highlights nine types of "illegal conduct," including the very three engaged in here:

"1. Billing for items or services not actually rendered";

"3. Upcoding"; and

"4. Duplicate billing."

Id. at DEF000698; *see also* App. No. 57.

On the following page, the Compliance Plan reemphasizes the importance of billing only for services that have been provided and properly documented:

Claim development and submission policies and procedures should:

1. provide for proper and timely documentation of all physician and other professional services prior to billing to ensure that only accurate and properly documented services are billed;
2. documentation will be maintained to support claims submitted and available for audit and review.
3. require that physician and hospital records and medical notes should support the submission and be appropriately organized in a legible form so they can be audited and reviewed;
4. diagnosis and procedures reported on the reimbursement claim be based on the medical record and other documentation, and that the documentation necessary for accurate code assignment be available to coding staff; and
5. Provide that the compensation for billing department coders and billing consultants should not provide any financial incentive to improperly up-code claims.

Ex. 20 at DEF000699.

The Compliance Plan also includes a section specific to "diagnostic laboratory testing services." *See* App. No. 58. That section even more specifically confirms PVA's knowledge that, with respect to its vascular laboratory diagnostic services, it should "bill[] for laboratory services **only after they are performed**." *Id.* at DEF000700 (emphasis added). It further affirms the requirement that: "The CPT or HCPCS code used by the billing staff **accurately describes the services that was ordered by the physician and performed**." *Id.*

PVA also has a "Policies and Procedures Manual" that reiterates, and adds to, these concepts. Policy Number 03 in the Manual is entitled "Up-coding." App. No. 59. It defines "Up-coding" as "the practice of selecting higher paying CPT®/HCPCS codes that are defined more accurately by lower paying CPT®/HCPCS codes." Ex. 20 at DEF000717. It states:

> **PERIPHERAL VASCULAR ASSOCIATES** understands that knowingly submitting up-coded claims to Medicare is considered to be Medicare program abuse. According to Medicare and CPT® general coding instructions, "a physician using CPT®-4 terminology and coding should select the name of the procedure or service that most accurately identifies the service performed."

Id. PVA's next policy, "Billing items or services not actually documented," is equally damning of its own practices:

> Documentation is the only proof that a service was provided. Each claim processed does not need documentation attached. However, a claim should not be submitted by **PERIPHERAL VASCULAR ASSOCIATES** if it is known that documentation does not exist and/or the service was not provided.
>
> HIPAA (Health Insurance Portability and Accountability Act) states that a person who has knowledge of a false claim and acts in deliberate or reckless disregard of the falsity of the information can be found to be a party to a false claim and be subject to civil and/or criminal penalties.

Ex. 20 at DEF000718.

PVA also has a policy entitled "Misuse of provider identification numbers," confirming its understanding that on the CMS-1500 form, "[t]he performing physician is the physician that

personally provides the service or supervision of the service. Services provided by anyone other than the physician whose PIN is claimed should not be claimed by [PVA]…" Ex. 20 at DEF000719 (emphasis added).

Several PVA employees testified that they had never seen PVA's compliance policies, or had never received any formal training on compliance. *See* App. No. 62. Dr. Alsabrook, PVA's Compliance Officer, testified that he had never seen PVA's compliance manual until he joined the coding compliance committee, years into his tenure at PVA. Ex. 1 (Alsabrook Dep. Tr.), at 19:15-19. Martha McGee, PVA's Billing Supervisor, who has been with PVA for 14 years, testified that PVA's "Medical Documentation and Coding Compliance Pledge" did not look familiar to her. Ex. 9 (McGee Depo Tr.), at 20:2-11.

b. ICAVL and ACR standards confirm that PVA's conduct was knowing and reckless.

PVA is accredited by the Intersocietal Accreditation Commission (IAC, formerly known as ICAVL). App. No. 64. IAC accreditation is relevant to Medicare reimbursement. App. No. 65The Local Coverage Determination for the services at issue, and covering Medicare in Texas, states in pertinent part:

> All non-invasive vascular studies must be:
> 1. Performed by a qualified physician; or
> 2. Performed under the general supervision of a qualified physician by a licensed* technologist who is certified in vascular technology; or
> 3. Performed in an **accredited** vascular laboratory.

Ex. 39 at ALEXANDER000076 (emphasis added). It continues: "Appropriate laboratory accreditation is limited to the American College of Radiology (ACR) Vascular Ultrasound Program, and the Intersocietal Accreditation Commission (IAC) . . . ." *Id.*

IAC accreditation is thus one option through which providers can meet the LCD's requirements. PVA, having chosen to comply with the LCD via IAC accreditation, is subject to its requirements.

The IAC standards are clear that physicians must review and interpret all studies within 48 hours of a patient visit, and that those interpretations must be documented and signed within 4 business days of a patient visit. Ex. 35 at DEF005836. PVA knew those standards, which are listed as required elements in its accreditation application. *See id.*; *see also* Ex. 49 ("IAC Standards and Guidelines for Vascular Testing Accreditation") §§ 3.1.2A ("A complete, accurate and signed final report must be generated [] as part of the record of examination"); 3.2A ("The report represents the final interpretation of the noninvasive examination and is part of the patient's legal medical record."); 3.2.7A (interpretation within two days; report within four).

The other Medicare-approved accreditation agency is the American College of Radiology (ACR). App. No. 67. ACR's guidelines also demonstrate the impropriety of PVA's practices. For example, ACR's detailed guidelines, entitled "ACR Practice Parameter for Communication of Diagnostic Imaging Findings," state, among other things:

- "Quality patient care can only be achieved when study results are conveyed in a timely fashion to those responsible for treatment decisions." (Ex. 23, p. 2)
- "An official interpretation (final report) by the interpreting physician must be generated and archived following any examination, procedure, or officially requested consultation regardless of the site of performance (hospital, imaging center, physician office, mobile unit, etc)." (p. 2)
- "The final report is the definitive documentation of the results of an imaging examination or procedure." (p. 3)

These guidelines are reiterated in at least two other ACR Practice Parameters: "Practice Parameter for Performing and Interpreting Diagnostic Ultrasound Examinations" (Ex. 51 at ALEXANDER001573) ("Adequate documentation is essential for high-quality patient care. There should be a permanent record of the ultrasound examination and its interpretation. . . . An official interpretation (final report) of the ultrasound examination should be included in the patient's medical record."); and "Practice Parameter for the Performance of Peripheral Venous Ultrasound Examination, which was "developed collaboratively by the American College of

Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the Society for Pediatric Radiology (SPR), and the Society of Radiologists in Ultrasound (SRU)" (Exh. 52 at ALEXANDER001582).

The standards of PVA's Medicare-approved accreditation agencies thus put PVA on notice that its documentation practices fell far outside of appropriate.

c. PVA's inpatient practices.

Apart from at its own vast chain of offices, PVA also performs services at several local hospitals, with which it is contracted to perform vascular studies. App. No. 70. For services performed at those hospitals, PVA actually follows the rules, completing written reports within—at most—48 hours of the study being performed, and always billing after a final report is complete in MedStreaming. *Id.* As summarized by Barbara Burrow in an internal e-mail entitled "Hospital Process," billing does not occur "until after [a vascular study] has reached the Final stage which indicates it has been signed off by a physician." Ex. 18; *see also* Ex. 2 (Burrow Dep. Tr.), 118:6-8; Ex. 13 ("Routine studies- Every effort will be made for the final interpretation to be available within 24 hours of the study completion.").

PVA also meticulously tracked its "Read Times" for interpretations of hospital-based studies, including identification and follow-up on any "Read Time Outliers," which it defined as "Routines read over 24 hrs after report completion." *See, e.g.,* Ex. 28 at DEF003022; *see also* App. No. 71. PVA feared running afoul of these hospital guidelines, and as discussed in Section II.F.4 below, knew that delays would risk patient health. *See* Ex. 34 ("Cardiologist is upset and patient is pending discharge without a final read in the system."); App. No. 71.

Unfortunately, PVA only followed the rules when somebody else was watching. In its own practice, outside of the hospitals, PVA's concerns with timeliness and appropriate billing practices evaporated.

d. Industry standards, reflected in a variety of readily available sources, confirm that PVA knowingly violated proper billing practices.

There is not a single industry publication that endorses, supports, or suggests PVA's billing practices. *See* App. No. 75. In contrast, there are innumerable industry publications, articles, and websites that confirm the appropriate and legal methods of reporting and billing, which are consistent across all areas of specialty that utilize diagnostic ultrasound. *Id.* Sources as varied as articles published by groups such as the American Institute of Ultrasound in Medicine (Ex. 42), American Urological Society (Ex. 43), Society of Point of Care Ultrasound (Ex. 48), textbooks such as Surgical and Interventional Ultrasound (Ex. 44), Medicare publications (Ex. 47), and coding guides published by ultrasound equipment manufacturers (Ex. 41), all show that PVA knew, or acted in deliberate ignorance, of the billing and documentation requirements that it violated. PVA's own compliance expert, Melissa Scott, could not identify a single industry publication that was contrary to the guidance in publications such as these. *See* Ex. 202 (Scott Dep. Tr.), at 81:21-82:5.

e. PVA's own expert, Dr. Collier, does not follow PVA's noncompliant reporting and billing practices.

PVA's expert, Dr. Paul E. Collier, is a vascular surgeon in Pennsylvania. App. No. 76. He owns and operates four vascular laboratories that perform vascular studies of the exact same type as PVA. App. No. 76. Dr. Collier, however, does not follow PVA's illegal billing practices. App. No. 77. Instead, he interprets and signs every vascular study within 24 hours, and never bills until he has done so:

> Q. Are there ever any situations where you review and sign more than 24 hours after the scan is complete?
>
> A. It would be unusual. It might be something that -- say I was, like, off on a Friday and I didn't check it until Monday. But usually, I check in pretty much every day, even if I'm on vacation. I still have to read them officially.
>
> Q. Are there any other situations at your practice where you -- your practice bills a payor for a vascular imaging study before the vascular lab report has been reviewed and signed by you? [Objection]

> A. In this day and age, I'd say -- I would have to say probably not. We -- since Streamline is hooked to our billing company, you know, to the best of my knowledge, they don't bill until I sign out on it. I think that's the way it's set up now with the billing company that we have. The billing company and Streamline are sort of -- I don't want to say one and the same, but they're sort of the same group that do it. So I think until I sign off on, like, an H&P or a vascular lab study, it doesn't get billed until the signature is on it.

Ex. 6 (Collier Dep. Tr.), at 39:14-40:15; *see also* App. No. 77.

Dr. Collier also has never engaged in PVA's "double-dipping" practice of billing for both an E/M service and a vascular study without completing two separate, stand-alone reports, one for the visit, and one for the interpretation. *Id.* at 43:17-44:7, 49:22-50:4; *see also* App. No. 78.

Similarly, one of PVA's former physicians, Dr. Lyssa Ochoa, who now owns and operates her own vascular practice, confirmed that in her own practice, she never bills until she has read and signed her MedStreaming reports:

> Q. So based on what you're saying, at your current practice at SAVE [(San Antonio Vascular and Endovascular Clinic)] do you ever bill for the global service, which would include the professional component related to ultrasound services at SAVE, before that final report is signed that you just mentioned?
>
> A. No.
>
> Q. And why is that?
>
> A. You cannot bill for the physician's services until you have finalized that report.

Ex. 8 (Ochoa Dep. Tr.), at 32:25-33:9; *see also* App. No. 68. Even one of PVA's current physicians, Dr. Lois Fiala, agreed that "having an separate and distinct, or standalone, report is important to completing the professional component associated with ultrasound studies." Ex. 5 (Fiala Dep. Tr.), at 45:12-19; *see also* App. No. 8.

4. PVA risked patient health and safety

The physician's interpretation and report is not only a billing requirement, it is a patient health imperative. Medicare does not reimburse for diagnostic tests used for "screening" purposes; i.e., patients must have a symptom or history that requires the vascular studies to be

performed. *See* Ex. 39 (LCD L35397) at ALEXANDER000074; App. No. 72. And, of course, the sonographers who conduct the studies are not qualified or licensed to interpret the studies or diagnose problems. App. No. 72. Accordingly, without a physician's interpretation, a vascular study is meaningless, and puts patient health and safety at risk. PVA knows this, which is why, in the hospital context, as described above, PVA is essentially fully compliant with the rules and industry standards. App. No. 72. But even in the hospital context, PVA sometimes slips up, and the consequences can be dire, as demonstrated in a 2017 e-mail from Dr. Alsabrook to other PVA physicians, in which he describes how a "deficit in inpatient vascular lab documentation and signing" led to "a near miss to negatively affect patient care." Ex. 17; *see also* App. No. 73.

Though this is a pure billing fraud case, any suggestion that PVA's practices were "harmless error" should be disregarded. The components included in the AMA's CPT codes are required for good reason—not just to prevent fraud, but to ensure good patient care.

III. ARGUMENT

A. Summary Judgment under the False Claims Act.

The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, prohibits persons from "knowingly" presenting or causing to be presented to the United States "a false or fraudulent claim for payment or approval," and from knowingly making or using false statements to obtain such payment. 31 U.S.C. § 3729 (a)(1), (2). The basic elements of an FCA violation are (1) a false statement or fraudulent course of conduct; (2) made with the requisite scienter ("knowingly"); (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due. *See United States ex rel. Longhi v. Lithium Power Technologies*, 575 F. 3d 458, 468 (5th Cir. 2009).

The FCA defines "knowingly" as acting with actual knowledge of falsity, with deliberate ignorance of the truth or falsity, or with reckless disregard of the truth or falsity. 31 U.S.C. § 3729(b). Specific intent to defraud is not required. *Id.* Congress intended for the FCA to apply to those who refuse "to learn of information which an individual, in the exercise of prudent

judgment, had reason to know." *UMC Electronics Co. v. United States*, 43 Fed. Cl. 776, 793 (Fed. Cl. 1999) (quoting S. REP. No. 99-345, at 21 (1986)).

"Reckless disregard" under the FCA is measured by an *objective* standard. *See United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) (reckless disregard "may be established without reference to the subjective intent of the defendant.").

Courts and Congress have repeatedly mandated that the FCA be applied liberally. As stated by the Fifth Circuit, "[b]ecause the FCA is 'remedial,' its provisions are to be construed 'broadly to effectuate its purpose.'" *U.S. ex rel. Bias v. Tangipahoa,* 816 F.3d 315, 324 (5th Cir. 2016) (quoting *U.S. ex rel. Rigsby v. State Farm Fire Cas. Co.*, 794 F.3d 457, 468 (5th Cir. 2015). The Act "has as its core function the promotion of transparency and honesty amongst government contractors." *U.S. v. Dynamics Research Corp.*, 2008 WL 886035, at *8 (D. Mass., March 31, 2008). The FCA embodies "the maxim that men must turn square corners when they deal with the Government." *U.S. ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 302 (6th Cir. 1989).

B. PVA's bills were "false."

Using a CPT code that misrepresents the services provided on a bill to Medicare is a factually "false" claim for purposes of the FCA, as it constitutes billing for services not performed, or misrepresenting the services performed. *See, e.g., U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009) ("Also alleged are specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedural Terminology code that would have been used in the bill."); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 662 (S.D. Tex. 2013); *United States ex rel. Emerson Park v. Legacy Heart Care, LLC*, No. 3:16-CV-0803-S, 2019 WL 4450371, at *9 (N.D. Tex. Sept. 17, 2019) ("Relator alleged that Remaining Defendants are liable under the FCA for 'upcoding [E&M] services to the highest level billing codes'—i.e., charging Medicare for unnecessary services or services that were never actually provided. A defendant charging the Government for services not actually provided is a staple FCA violation."); *United States v.*

Wagoner, No. 2:17-CV-478-TLS, 2018 WL 4539819, at *5 (N.D. Ind. Sept. 20, 2018); *United States ex rel. Turner v. Michaelis Jackson & Assocs.*, No. 03-CV-4219-JPG, 2007 WL 496384, at *7 (S.D. Ill. Feb. 13, 2007) ("relators have shown why the bill submitted to Medicare was false: it was billed pursuant to CPT 99213 rather than CPT 66984"); *Krizek*, 859 F. Supp. at 7–8 ("The submission of a claim on the HCFA 1500 form is a certification by the provider to the government of the correctness of the information submitted and, among other things, that the services were performed by the provider, and that the provider will maintain 'such records as are necessary to disclose fully the extent of the services provided....'").

As described above, PVA used the wrong CPT codes for vascular studies in two ways: (1) PVA billed using "global" CPT codes for vascular studies that misrepresented that a physician's interpretation and reporting had been rendered; and (2) PVA billed for both an "Evaluation and Management" patient visit and a vascular study on the same day, without having completed a separate, stand-alone report reflecting performance of the professional component (i.e., double billing).

It is undisputed that when it billed using the global CPT codes, PVA was representing that it had completed a physician's interpretation, and a written report reflecting the physician's interpretation. Yet for 24.2% of its global billings, a PVA physician had not prepared and signed a final report in MedStreaming. PVA was thus falsely representing via submission of the global CPT codes that it had rendered the complete global service.

In response, PVA argues that in those instances its physicians' written reports exist outside of MedStreaming, in the notes that accompany a patient visit. As described above, this defense fails for two reasons.

First, as detailed above in Section II.E.1, for "testing only" patients, there was no patient visit. Accordingly, the only place that a PVA physician could have documented their interpretation was in a MedStreaming final report. For 8,757 global CPT claims to Medicare, there was no patient visit, and no MedStreaming report. All of those claims are false.

Second, as detailed above in Section II.E.2, for patients who had both a vascular study and an Evaluation and Management visit, the vascular study cannot be billed for in addition to the E/M code unless there is a separate, stand alone report reflecting a physician's interpretation. By billing for the vascular study on a global basis in these instances, PVA was representing that it completed the entire service described in the CPT manual, when it had not. These claims too are false.

In addition, the claims that PVA submitted under the wrong provider's name are also false. As detailed above, PVA's practices and delays inevitably led to its bills representing the wrong "rendering" physician. App. No. 18. As many courts have confirmed, billing under the wrong physician's name constitutes a false claim. As explained in *United States v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001), placing the wrong physician's information in the performing provider field of the CMS-1500 form is a representation that the physician "was the performing physician or supplier and therefore constituted a false statement." *Id.* This holds true even where the services were actually rendered: "a claim may be false even if the services billed were actually provided, if the purported provider did not actually render or supervise the service." *United States v. Mackby*, 261 F.3d 821, 826 (9th Cir. 2001) (citing *Peterson v. Weinberger,* 508 F.2d 45, 52 (5th Cir.1975)).

Here, with respect to 1,690 claims, PVA not only submitted global CPT codes when the physician had not completed and documented their interpretation, but PVA also billed under the wrong rendering physician. Those claims were false for purpose of the FCA.

C. PVA's false statements were material.

Billing for services not rendered is always "material" for purposes of the FCA. As to materiality, the Fifth Circuit requires only "proof only that the defendant's false statements could have influenced the government's pay decision or had the potential to influence the government's decision, not that the false statements actually did so." *U.S. ex rel. Harman v. Trinity Industries Inc.*, 872 F.3d 645, 661 (5th Cir. 2017); *see also U.S. ex rel. Longhi Lithium Power Technologies*, 575 F.3d 458 (5th Cir. 2009). As detailed above, Medicare reimburses for

services rendered based on charges submitted by providers on the CMS-1500 form, using CPT codes. The CPT codes determine the amount of money that Medicare reimburses the provider. There is no other mechanism or documentation that triggers Medicare's reimbursement. Accordingly, there can be no dispute that the CPT codes submitted by PVA "could have influenced the government's pay decision." *See id.*

Moreover, Medicare makes clear in various publications that it considers billing for services not rendered, and naming the wrong provider,[3] to be quintessential examples of fraud and abuse. For example, CMS publishes a manual for providers entitled "Medicare Fraud & Abuse: Prevent, Detect, Report," which reminds providers, among other things:

- "**When you submit a claim for services provided to a Medicare beneficiary, you are filing a bill with the Federal Government and certifying you earned the payment requested and complied with the billing requirements**."
- "Examples of improper claims include: . . . Billing codes that reflect [] a more expensive treatment than was provided. . . . Billing services not provided. . . . Billing separately for services already included in a global fee, like billing an evaluation and management service the day after surgery."
- "'If you didn't document it, it's the same as if you didn't do it.' The same can be said for Medicare billing."

Ex. 204, at 11 (emphasis in original)

The Medicare Program Program Integrity Manual, Chapter 4 – Program Integrity, similarly provides a detailed list of "Examples of Medicare Fraud," including all of those at issue here:

- "Incorrect reporting of diagnoses or procedures to maximize payments;"
- "Billing for services not furnished and/or supplies not provided."

[3] A 2013 e-mail string also confirms that PVA knows its charges must be billed under the physician who actually read the study. *See* Exh. 16 ("Dr. Macris is the one who read the study, so the lab should be billed under him.").

- "Misrepresenting dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services;"

Ex. 205, § 4.2.1. These publications confirm the materiality to Medicare of these practices.

D. PVA acted knowingly.

As detailed above in Section II.F, PVA acted recklessly, and even with actual knowledge, that it was submitting false claims.

As recently emphasized by the Fifth Circuit, "presence of an intent issue does not automatically preclude summary judgment; the case must be evaluated like any other to determine whether a genuine issue of material fact exists." *United States ex rel. Drummond v. BestCare Lab. Servs., L.L.C.*, 950 F.3d 277, 281 (5th Cir. 2020) (quoting *Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1326 (5th Cir. 1996)). In *Drummond*, the defendants argued that their "good-faith reliance on the CMS Manual creates a genuine fact dispute about whether they had the requisite mental state to violate the False Claims Act." *Id.* The Fifth Circuit rejected the argument, holding that "there is no plausible reading of the CMS Manual that could support the defendants' billing practices." *Id.*

So too here, there is no "plausible reading" of the CPT manual, or any Medicare guidance, that could justify PVA's practices. To the contrary, as detailed above in Sections II.F.3.d every Medicare and industry publication that touches on the issues makes clear that PVA's practices were out of bounds. Even PVA's own expert, Dr. Collier, does not follow PVA's practices in his vascular labs. *See, supra*, § II.F.3.e. Most notably, as detailed in Section II.F.1, in 2017 PVA embarked on a short-lived "Compliance" project to increase the speed at which studies were read, and to **"Allow[] for Compliance," by "billing after study interpreted."** Ex. 30 at DEF007691 (emphasis added). PVA knew that its practices were not compliant, but valued cash flow above all else.

E. PVA's claims caused the government to pay out significant moneys.

The amounts that PVA's false claims caused the government to pay out are detailed in the work of Relators' data expert, Dr. Nye, and summarized as follows.

"Testing-Only": As to the "testing only" patients for which PVA submitted vascular study global CPT codes without a physician interpretation and report, the number of false claims, and resulting reimbursements, are as follows:

	Reimbursements[4]	***False Claims***
Medicare Part B:	$433,218	4,924
Medicare Railroad Part B:	$2,249	32
Medicare Advantage Plans:	$356,893	3,784
Tri-Care:	$28,533	25[5]
Total:	**$820,893**	**8,757**

See Ex. 207 (data extracted from Exhibits 10a and 10b of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out[6]).

"Double Dipping": As to testing and E/M visit patients for which PVA submitted vascular study global CPT codes without a separate, stand-alone physician interpretation and report, the number of false claims, and resulting reimbursements, are as follows:

	Reimbursements	***False Claims***
Medicare Part B:	$2,744,447	29,954
Medicare Railroad Part B:	$17,475	195
Medicare Advantage Plans:	$5,424,053	25,301
Tri-Care:	$184,020	116
Total:	**$5,625,548**	**55,566**

[4] Reimbursements (i.e., payments received by PVA) are reflected as negative values in PVA's data and Dr. Nye's summaries, but listed as positive values here. There are also a limited number of "Takebacks" contained in PVA's data and Dr. Nye's summaries. The figures here incorporate those "Takebacks."

[5] Most claims to Tri-Care are characterized in PVA's data as secondary payor claims. Reimbursements from secondary payors are not captured in the claim count of Dr. Nye, to be conservative and avoid duplicate claim counts. Accordingly, Relators do not seek statutory penalties for claims to secondary payors.

[6] These figures are based on conservative assumptions when filtering out non-Medicare-related payors from Dr. Nye's results. Accordingly, should the case proceed to trial, this figures may increase.

See Ex. 207 (data extracted from Exhibits 4d Supplemental and 11 of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out).

Wrong Provider: As to all of the vascular study charges in the "testing only" and "double dipping" categories, where PVA submitted a vascular study global CPT code under the name of a physician who did not ultimately read the study, the number of false claims, and resulting reimbursements, are as follows:

	Reimbursements	***False Claims***
Medicare Part B:	$86,635	962
Medicare Railroad Part B:	$231	3
Medicare Advantage Plans:	$75,405	721
Tri-Care:	$5,599	4
Total:	**$167,870**	**1,690**

See Ex. 207 (data extracted from Exhibits 9a and 9b of the Second Supplemental Report of Dr. Nye, with non-federal and non-Medicare payors filtered out).

Treble damages and statutory penalties on the foregoing figures are mandatory. *See* 31 U.S.C. § 3729(a)(1).

IV. CONCLUSION

For the foregoing reasons, Relators respectfully request that the Court grant Summary Judgment, or in the alternative, Partial Summary Judgment on the categories of claims, and issues, identified above.

Dated: August 21, 2020

By: */s/ Justin T. Berger*

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of August, 2020, I electronically filed the foregoing instrument with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following counsel of record:

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